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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/058,589	04/10/1998	IAN KIMBER	138.41.US01	7637

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/058,589	KIMBER ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-10,21,23,24 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10,21,23,24 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted September 1, 2004 is acknowledged.

Claims Rejection 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-10, 21, 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Morinaga Milk Inc. (JP 07-233086), and De Lacharriere et al. (US Patent 5,658,581).

2. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

3. Teng et al. does not teach expressly the treatment of the particular dermal disorder herein or the employment of biological analog or fragments of lactoferrin.

However, Britigan teaches generally that lactoferrin are known to be useful as an anti-inflammatory agent. See, particularly, page 151, the summary and conclusion. Morinaga Milk Inc. teaches that lactoferrin or its derivatives are known to be useful for treating various skin disorders, including allergic dermatitis. See, the abstract. De Lacharriere et al. teach that lactoferrin is known to be useful for treating or preventing skin inflammation induced by certain

cosmetic or pharmaceutical allergen, See, particularly, the abstract, column 3, line 4 bridging column 4, line 39, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lactoferrin for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis.
A person of ordinary skill in the art would have been motivated to employ lactoferrin for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis because lactoferrin is well known to be useful for anti-inflammation, and is further known particularly useful for treatment of skin inflammation, particularly, allergic dermatitis. Regarding the functional limitation in claim 7, i.e., "a local immune response characterized by increased production of TNF-α" and in claim 21, "a dermal inflammatory response that is characterized by accumulation of dendritic cell in lymph nodes", note such limitation is not seen to render the claimed invention any patentable weight since the ultimate method, e.g., administering lactoferrin to person with dermal inflammatory disorder such as contact dermatitis, UV-induced inflammation, psoriasis, skin aging or diaper rash, is not further limited by such functional language. Further, a method for treatment of a symptom would have been reasonably expected to be effective for the treatment of the symptom despite the underline etiology that causes the symptom. Finally, the optimization of a result effective parameter, e.g., effective amount of therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. As to the newly added limitation "that is exposed to an allergen," note allergic dermatitis is caused by exposing to allergen. Regarding the limitation "a composition consisting essentially of lactoferrin and a pharmaceutically acceptable carrier," note,

absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). Further, since lactoferrin has been taught or suggested to be useful in treating dermal inflammation, it would have been obvious to one of ordinary skill in the art to make a composition, wherein lactoferrin is the active ingredient. In fact, in De Lacharriere et al. (US Patent 5,658,581), lactoferrin is used as the only anti-inflammatory agent.

Response to the Arguments

Applicants' amendments and remarks submitted September 1, 2004 have been fully considered, but are not persuasive.

4. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejections are base on the teachings from the combined four references. Taking the teaching as a whole, one of ordinary skill in the art would have view the claimed invention as obvious. Applicants assert that the Teng et al. and Britigan et al do not teach or suggest the use of lactoferrin to treat an allergen-induced inflammatory response. The examiner disagrees. First, Teng et al. teach a method of conditions in a patient characterized by deficiency in lactoferrin. Skin infection is one of the exemplified conditions. Britigan et al. disclosed the usefulness of lactoferrin as anti-

inflammatory agents. Britigan et al. do not exclusively define that lactoferrin would only be useful for inflammation caused by microorganisms. Britigan et al. do suggest that lactoferrin may play a role in ameliorating LPS-induced toxicity. However, that is only one aspect of lactoferrin. Britigan et al. state: "In summary, the current data strongly suggests that among its potential roles in vivo, lactoferrin may serve as an antioxidant defense mechanism at at least two levels. First by binding any catalytic iron which may be generated during the course of cell destruction. During an inflammatory response it may serve to prevent hydroxy-radical mediated tissue injury asociated with neutrophill-oxidant production." Obviously, the inflammation herein referred is not limited to infection-induced inflammation. In fact the combination of Teng et al. Britigan et al. and Morinaga Milk fairly suggest the usefulness of lactoferrin as anti-inflammatory agent. De Lacharriere et al. further provide suggestion that lactoferrin would be useful in preventing or treating allergen-induced inflammation. De Lacharriere particularly teach to use lactoferrin an antagonist for those cosmetic or pharmaceutical ingredients inducing allergic action.

As to the newly added limitation "that is exposed to an allergen," and the teaching disclosed by Morinaga Milk, note allergic dermatitis is caused by exposing to allergen. Regarding the limitation "a composition consisting essentially of lactoferrin and a pharmaceutically acceptable carrier," note, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in

the basic and novel characteristics of the invention."). Further, since lactoferrin has been taught or suggested to be useful in treating dermal inflammation, it would have been obvious to one of ordinary skill in the art to make a composition, wherein lactoferrin is the active ingredient. In fact, in De Lacharriere et al. (US Patent 5,658,581), lactoferrin is used as the only anti-inflammatory agent.

5. Regarding De Lacharriere reference, note the patent specifically use lactoferrin as an antagonist. See the claims.

6. No claim is allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617